

EnzymaticTherapy

NATURAL MEDICINES®

March 29, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Pearl Essence™	Dietary Supplement a special blend of friendly bacteria to support healthy digestion*	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

3v:

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/29/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

975 0162 LET 13986

Sincerely,

een Bay, WI 54311-8328 Michael P. Devereux

Chief Financial Officer

Pearl Essesnce le

825 Challenger Drive Green Bay, WI 54311-8328

Ph: 920-469-1313

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM
Pearl Essence™	Pearl Essence with patented True	REFERS Proprietary Probiotic Blend
	Delivery™ Technology protects the Lactobacillus acidophilus and Bifidobacterium longum from stomach acids, and guarantees delivery in the intestine, where they are released intact to increase healthy intestinal flora.*	Lactobacillus acidophilus and Bifidobacterium longum

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:	1
,	Robert Doster
Title:	Senior Vice President of Scientific Affairs
	•
Date:	3/30/04

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Green Bay, WI 54311-8328

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Pearl Essesnce 2e

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Michael P. Devereux Chief Financial Officer